

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC. and)	
JAZZ PHARMACEUTICALS IRELAND)	
LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 21-1138 (MN)
)	
AVADEL PHARMACEUTICALS PLC,)	
AVADEL US HOLDINGS, INC., AVADEL)	
SPECIALTY PHARMACEUTICALS, LLC,)	
AVADEL LEGACY PHARMACEUTICALS,)	
LLC, AVADEL MANAGEMENT)	
CORPORATION and AVADEL CNS)	
PHARMACEUTICALS LLC,)	
)	
Defendants.)	

JAZZ PHARMACEUTICALS' ANSWER TO
AVADEL CNS PHARMACEUTICALS LLC'S COUNTERCLAIMS

Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz Pharmaceuticals"), by their undersigned attorneys, hereby answer the Counterclaims to their Complaint for Patent Infringement by Defendant Avadel CNS Pharmaceuticals LLC ("Avadel"), dated September 9, 2021 (the "Counterclaims"), as follows. Except as expressly admitted, all allegations are denied.

AVADEL'S COUNTERCLAIMS

1. Defendants' Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 1 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that this Court has subject matter jurisdiction over Avadel's counterclaims as to US. Patent No. 11,077,079 (the "'079 patent"),

denies that Avadel is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 1.

2. The Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338.

ANSWER: Paragraph 2 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that this Court has subject matter jurisdiction over Avadel's counterclaims as to the '079 patent, denies that Avadel is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 2.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400(b).

ANSWER: Paragraph 3 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that venue is proper to adjudicate this action and, except as so admitted, denies the allegations of paragraph 3.

4. Counterclaim-Plaintiff Avadel CNS Pharmaceuticals, LLC ("Avadel") is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005.

ANSWER: Jazz Pharmaceuticals admits on information and belief the allegations of paragraph 4.

5. Upon information and belief, Counterclaim-Defendant Jazz Pharmaceuticals, Inc. ("Jazz") is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 3170 Porter Drive, Palo Alto, California 94304.

ANSWER: Jazz Pharmaceuticals admits the allegations of paragraph 5.

AVADEL'S PRELIMINARY STATEMENT

6. Flamel Ireland Limited, a wholly-owned subsidiary of Avadel Pharmaceuticals [sic] plc, owns numerous United States patents that cover Avadel's innovative product FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. One of those patents, U.S. Pat. No. 10,952,986 (the "'986 patent"), entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Involved Pharmacokinetics," was filed on May 23, 2019 as application number 16/420,321 (the

“’321 application”), and issued on March 23, 2021. The ’321 application claims priority to several provisional applications with the earliest provisional application No. 62,365,812 filed on July 22, 2016.

ANSWER: Jazz Pharmaceuticals admits on information and belief that Flamel Ireland Limited is a wholly-owned subsidiary of Avadel Pharmaceuticals plc. Jazz Pharmaceuticals further admits that U.S. Patent No. 10,952,986 (the “’986 patent”) is titled, “Modified release gamma-hydroxybutyrate formulations having improved pharmacokinetics,” lists May 23, 2019 as the filing date as application number 16/420,321 (the “’321 application”), and lists March 23, 2021 as the issue date. Jazz Pharmaceuticals further admits that the ’321 application claims priority to three provisional applications, the earliest of which is provisional application number 62/365,812, for which the ’986 patent lists July 22, 2016 as the filing date. Jazz Pharmaceuticals lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 6 and, therefore, denies those allegations.

7. At the time the ’321 application was published on September 12, 2019, Jazz had not filed the patent application that ultimately issued as Jazz’s asserted ’079 patent.

ANSWER: Jazz Pharmaceuticals admits that the ’986 patent lists September 12, 2019 as the publication date of the underlying ’321 application. Jazz Pharmaceuticals further admits that the ’079 patent issued from an application filed on December 10, 2020, which claimed priority to three earlier-filed applications, including an earliest non-provisional application filed on February 18, 2016 and an earliest provisional application filed on February 18, 2015, and, except as so admitted, denies the allegations of paragraph 7.

8. Jazz did not file the application that ultimately led to the issuance of the ’079 patent until December 10, 2020 – more than a year *after* the ’321 application was published.

ANSWER: Jazz Pharmaceuticals admits that the ’986 patent lists September 12, 2019 as the publication date of the underlying ’321 application. Jazz Pharmaceuticals further admits that the ’079 patent issued from an application filed on December 10, 2020, which claimed priority to

three earlier-filed applications, including an earliest non-provisional application filed on February 18, 2016 and an earliest provisional application filed on February 18, 2015, and, except as so admitted, denies the allegations of paragraph 8.

9. On information and belief, Jazz drafted the claims that ultimately issued as the '079 patent based not on any commensurate disclosure of its underlying application, but solely in view of the disclosures set forth in the '321 application. The '079 patent specification only discloses embodiments of a formulation for purported once-daily dosing that utilize one or more ion exchange resins. And yet, Jazz has asserted that one or more claims of the '079 patent would be infringed through the use of Avadel's FT218, which does not include any such ion exchange resin. Given Jazz's view of the claim scope of the '079 patent, the '079 patent claims as filed and issued are neither described nor supported by its specification as, on information and belief, the claims were instead solely based on Flamel Ireland Limited's inventive work disclosed in at least the '321 application.

ANSWER: Jazz Pharmaceuticals admits on information and belief that the use of Avadel's proposed sodium oxybate product, code named FT218, would infringe one or more claims of the '079 patent, refers to the text and claims of the '079 patent for the contents thereof, and, except as so admitted, otherwise denies the allegations of paragraph 9.

Count I: Declaratory Judgment of Alleged Non-Infringement of the '079 Patent

10. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

11. An actual controversy exists between Avadel and Jazz over the alleged infringement of at least one claim of the '079 patent. Jazz holds itself out as the owner of the '079 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

ANSWER: Paragraph 11 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '079 patent, that Jazz Pharmaceuticals owns the '079 patent, that Avadel's filing of a New Drug Application ("NDA")

to commercially market Avadel's proposed sodium oxybate drug product before the '079 patent expires infringes at least claim 1 of the '079 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '079 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 11.

12. The submission of Avadel's NDA does not infringe the '079 patent in violation of 35 U.S.C. § 271(e), either literally or under the doctrine of equivalents. The making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States would not infringe any valid claim of the '079 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), either literally or under the doctrine of equivalents. Avadel hereby seeks a declaration that the submission of Avadel's NDA, and the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States does not infringe and/or will not infringe any valid claim of the '079 patent.

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration that the claims of the '079 patent are not infringed, denies that Avadel is entitled to the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 12.

13. Avadel has not infringed, is not infringing, and will not infringe any valid claim of the '079 patent, directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. A judicial declaration is necessary and appropriate so that Avadel may ascertain its rights regarding the '079 patent.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 13.

Count II: Declaratory Judgment of Alleged Invalidity of the '079 Patent

14. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

15. An actual controversy exists between Avadel and Jazz over the invalidity of the '079 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

ANSWER: Paragraph 15 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that a justiciable controversy exists between Avadel and Jazz Pharmaceuticals regarding the '079 patent, that Avadel's filing of an NDA to commercially market Avadel's proposed sodium oxybate drug product before the '079 patent expires infringes at least claim 1 of the '079 patent under 35 U.S.C. § 271(e), that the making, using, offering to sell, selling, and/or importation of Avadel's proposed sodium oxybate drug product will infringe at least claim 1 of the '079 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), and, except as so admitted, denies the allegations of paragraph 15.

16. All claims of the '079 patent are invalid because they fail to comply with one or more requirements of the United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103, 112, 115, and/or 116. Avadel expressly reserves all rights to identify and assert additional invalidity positions in this case.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 16.

17. Avadel hereby seeks a declaration that the claims of the '079 patent are invalid.

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek a declaration that the claims of the '079 patent are invalid, denies that Avadel is entitled to the relief that it seeks and, except as so admitted, denies the allegations of paragraph 17.

Count III: Alleged Inequitable Conduct

18. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

Avadel's Background

19. Avadel, not Jazz, invented a once-nightly formulation of sodium oxybate. Jazz is not the true inventor of the subject claims. It derived the alleged invention from Avadel, and it concealed that fact from the patent Examiner in order to obtain the '079 patent.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 19.

20. During prosecution of the '079 patent, Jazz owed a duty of candor requiring it to disclose to the Examiner all information material to patentability. This duty included, but was not limited to, a specific duty to tell the Examiner if Jazz copied claims from another patent or application. Jazz copied various claims in the '079 patent from one of Avadel's prior patent applications. But Jazz did not disclose its copying to the Examiner, and indeed did not even tell the Examiner about the existence of Avadel's application at all until a supplemental disclosure just months before the '079 patent issued, despite disclosing more than 200 other, less relevant prior art references. Jazz concealed its copying, and buried the reference to Avadel's application, with the specific intents of both hiding the fact that the named Jazz inventors did not invent the subject matter claimed in the '079 patent, and misleading the United States Patent and Trademark Office ("PTO") into issuing the '079 patent.

ANSWER: Paragraph 20 states a legal conclusion for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals admits that the applicants for the application that issued as the '079 patent disclosed Avadel's '986 patent to the United States Patent and Trademark Office ("PTO") in an Information Disclosure Statement filed on April 27, 2021, refers to the text, claims, and file history of the '079 patent for the contents thereof, and, except as so admitted, otherwise denies the allegations of paragraph 20.

21. Had the Examiner known the truth, the PTO would not have issued the '079 patent to Jazz for various reasons, including lack of written description and for lack of novelty under § 102 in light of Avadel's earlier-filed application. And because it is impossible to conceive of a reason to hide Jazz's copying from the Examiner other than as part of an effort to mislead the Examiner, the natural and most reasonable inference is that Jazz did so with an intent to deceive the PTO. Jazz's concealment breached its duty of candor to the PTO and renders the '079 patent unenforceable.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 21.

22. Avadel has been awarded multiple patents in connection with its revolutionary new once-nightly formulation of sodium oxybate.

ANSWER: Jazz Pharmaceuticals admits on information and belief that certain of Avadel's patents, including U.S. Patent No. 10,272,062 (the "'062 patent"), cover Avadel's proposed sodium oxybate product, code named FT218. Jazz Pharmaceuticals lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 22 and, therefore, denies those allegations

23. As discussed above, on May 23, 2019, Flamel Ireland Limited filed the '321 application, which eventually issued as the '986 patent on March 23, 2021.

ANSWER: Jazz Pharmaceuticals admits that Avadel's '986 patent lists May 23, 2019 as the filing date as the '321 application, and lists March 23, 2021 as the issue date. Jazz Pharmaceuticals lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 23 and, therefore, denies those allegations.

24. Flamel Ireland Limited is today known as Avadel Ireland.

ANSWER: Jazz Pharmaceuticals admits on information and belief the allegations of paragraph 24.

25. Unlike the specification of Jazz's '079 patent, the specification of Avadel's '321 application contains detailed information regarding modified release formulations of oxybate and methods of using those formulations therapeutically. For example, whereas Jazz's '079 patent has no figures whatsoever, no dissolution testing, and no examples in which humans or any other animal were treated, the specification of Avadel's '321 application contains 90 figures, detailed dissolution testing, and detailed data from in vivo studies.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file histories of the '079 patent and the '321 application for the contents thereof, and otherwise denies the allegations of paragraph 25.

26. As of the May 23, 2019 filing date of the Avadel '321 application, Jazz had not filed the application leading to the '079 patent—application number 17/118,041 (the "'041 application"). Nor had it filed the parent application to the '041 application; application number 16,448,598 was filed on June 21, 2019. It had filed a *grandparent* application, application number 15/047,586 (the "'586 application"), on February 18, 2016, which would eventually issue as U.S. Patent No. 10,398,662 (the "'662 patent"). That grandparent application in turn derived from a provisional application, 62/117,889 (the "'889 provisional application"), which was filed on February 18, 2015.

ANSWER: Jazz Pharmaceuticals admits that the '986 patent lists May 23, 2019 as the filing date of the underlying '321 application. Jazz Pharmaceuticals further admits that the '079 patent issued from application number 17/118,041 (the "'041 application") filed on December 10, 2020, which claimed priority to application number 16/448,598 filed on June 21, 2019,

application number 15/047,586 (the “ ’586 application”) filed on February 18, 2016, and provisional application number 62/117,889 (the “ ’889 application”) filed on February 18, 2015. Jazz Pharmaceuticals further admits that the ’586 application issued as U.S. Patent No. 10,398,662 (the “ ’662 patent”) on September 3, 2019, and, except as so admitted, denies the allegations of paragraph 26.

27. The claims of the Avadel ’321 application first became publicly available when the ’321 application was published by the PTO on September 12, 2019. Some of the claims were slightly modified during prosecution, and the final version of the claims that are found in the ’986 patent became publicly available when an Avadel Amendment and Response to Non Final Office Action filed October 1, 2020 was published.

ANSWER: Jazz Pharmaceuticals admits that the ’986 patent lists September 12, 2019 as the publication date of the underlying ’321 application. Jazz Pharmaceuticals lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 27 and, therefore, denies those allegations.

28. Approximately two months later, on December 10, 2020, Jazz filed the ’041 application, which eventually issued as the ’079 patent. Along with Jazz’s filing of the ’041 application, Jazz filed a Nonpublication Request. Both the ’041 application and the Nonpublication Request were signed by Jazz’s outside counsel, Jason C. Valentine (“Mr. Valentine”).

ANSWER: Jazz Pharmaceuticals admits that the ’041 application was filed on December 10, 2020, refers to the text, claims, and file history of the ’041 application for the contents thereof, and, except as so admitted, otherwise denies the allegations of paragraph 28.

29. By its Nonpublication Request, Jazz sought to ensure that the ’041 application would not be made public, as would ordinarily take place after the expiration of a certain period of time following the filing of the application. As of the December 10, 2020 filing date of the ’041 application and the Nonpublication Request, the specification of the ’041 application had already been made public at least through the issuance of the ’662 patent, as the ’662 patent issued on September 3, 2019. Two new paragraphs were added to the specification of the ’041 application, but Jazz represented to the Examiner that the paragraphs being inserted were “material previously incorporated by reference” and so were also previously publicly available. Accordingly, taking Jazz’s argument at face value, the only reasonable inference that can be drawn from the filing of the Nonpublication Request with respect to the ’041 application is that Jazz was seeking to prevent others from learning what claims Jazz was pursuing in the ’041

application. Those claims were literally the only thing in the “nonpublished” patent application that were not already published. On information and belief, Jazz sought to prevent Avadel in particular from learning that the claims that Jazz was pursuing were largely copied from Avadel’s ’321 application.

ANSWER: Jazz Pharmaceuticals admits that the specification of the ’041 application had already been made public at least through the issuance of the ’662 patent, that the ’662 patent issued on September 3, 2019, that a December 21, 2020 preliminary amendment to the ’041 application added two paragraphs to the specification of the ’041 application that were previously incorporated by reference, and otherwise denies the allegations of paragraph 29.

30. The table below shows the first seven claims of Avadel’s ’321 application on the left and the first seven claims of Jazz’s later filed ’041 application on the right.

Claims from Avadel’s Patent Application No. 16/420,321, Amendment and Response to Non Final Office Action, filed October 1, 2020	Claims from Jazz’s Patent Application No. 17/118,041, filed December 10, 2020
1. A method of treating a disorder treatable with gamma-hydroxybutyrate in a human in need thereof, the method comprising administering a single daily dose to said human, the single daily dose comprising an amount of gamma-hydroxybutyrate equivalent to from 3.0 to 12.0 g of sodium oxybate, wherein the administering comprises opening a sachet containing a gamma-hydroxybutyrate formulation, mixing the formulation with water, and orally administering the mixture.	1. A method of treating a disease or condition treatable with oxybate in a patient in need thereof, the method comprising: administering a single daily dose to the patient, the single daily dose comprising an amount of oxybate equivalent to from 4.0 g to 12.0 g of sodium oxybate, wherein the administering comprises opening a sachet containing an oxybate formulation, mixing the formulation with water, and orally administering the mixture to the patient.
2. The method of claim 1, wherein the orally administering occurs at bedtime.	2. The method of claim 1, wherein the orally administering occurs at night.
3. The method of claim 1, wherein the mixing occurs shortly before the orally administering.	3. The method of claim 1, wherein the oxybate formulation is mixed with water immediately prior to administration.
4. The method of claim 1, wherein the orally administering occurs approximately 2 hours after said human has eaten a meal.	4. The method of claim 1, wherein the oxybate is administered with food.

5. The method of claim 1, wherein said administering results in inducing said human to sleep for 6 to 8 hours.	5. The method of claim 1, wherein the administering promotes the patient to sleep for 6 to 8 hours.
6. The method of claim 1, wherein the amount of gamma-hydroxybutyrate administered to the human is equivalent to 4.5 g, 6.0 g, 7.5 g or 9.0 g of sodium oxybate.	6. The method of claim 1, wherein the amount of oxybate administered to the human is 35 mEq, 45 mEq, 60 mEq, or 70 mEq of oxybate.
7. The method of claim 1, wherein the mixture is a suspension.	7. The method of claim 1, wherein the mixture is a suspension.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file histories of the '041 application and the '321 application for the contents thereof, and otherwise denies the allegations of paragraph 30.

31. As is clear from a side-by-side comparison, claims of Jazz's '041 application that issued as the '079 patent are strikingly similar to publicly available claims of Avadel's '321 application. The similarity is far too close to be accidental. The only reasonable explanation is that Jazz copied Avadel's claims.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '079 patent for the contents thereof, and otherwise denies the allegations of paragraph 31.

32. The breadth and depth of such copying cannot be the result of happenstance. On information and belief, Jazz, through its agent Mr. Valentine, intentionally copied the Avadel claims.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '079 patent for the contents thereof, and otherwise denies the allegations of paragraph 32.

33. Jazz and Mr. Valentine never disclosed to the Examiner that they had copied claims in Jazz's '041 application from Avadel's '321 application.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 33.

34. On December 21, 2020, Jazz filed an Information Disclosure Statement ("IDS") signed by Mr. Valentine that listed 204 references but did not include Avadel's '321 application.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 34.

35. On February 24, 2021, the Examiner issued a Non-Final Rejection, rejecting all claims of the '041 application as being invalid under 35 U.S.C. § 103.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 35.

36. On March 3, 2021, Avadel's '986 patent issued.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 36.

37. On April 26, 2021, an applicant-initiated interview with the Examiner took place via video conference. Mr. Valentine participated in the interview for Jazz, as did Phil McGarrigle (another attorney of record for Jazz) and named inventor Clark Allphin. At the interview, Jazz, through Mr. Valentine, Mr. McGarrigle, and Mr. Allphin, argued that sachet dosages like those recited in the claims were not obvious.

ANSWER: Jazz Pharmaceuticals admits that an interview with the Examiner for the '041 application took place on April 26, 2021, refers to the text, claims, and file history of the '041 application for the contents thereof, and, except as so admitted, otherwise denies the allegations of paragraph 37.

38. A slide deck made of record in the file history of the '041 application demonstrates that Mr. Valentine and/or Mr. McGarrigle told the Examiner that the '041 application was a part of Jazz's patent portfolio that "goes back to 1999." They represented to the Examiner that a sachet containing a solid, once-nightly unit dose product represented an advance for patients with respect to convenience, compliance, and safety. They then argued that the prior art cited by the Examiner did not provide a motivation to prepare such a sachet formulation. On information and belief, none of Mr. Valentine, Mr. McGarrigle, or Mr. Allphin informed the Examiner during this interview of (1) the existence of the '321 application; (2) that Jazz had copied the claims of the '041 application from Avadel's '321 application; (3) that they had not in fact invented a once-nightly formulation of oxybate in 1999 or at any time thereafter, and (4) that it was Avadel and not Jazz that had developed a sachet formulation of oxybate.

ANSWER: Jazz Pharmaceuticals admits that the Examiner interview summary record for the April 26, 2021 interview contains an attached presentation, refers to the text, claims, and file history of the '041 application for the contents thereof, and, except as so admitted, otherwise denies the allegations of paragraph 38.

39. On April 27, 2021, Jazz filed an Information Disclosure Statement ("IDS") signed by Mr. Valentine that listed 33 references, including Avadel's '321 application and Avadel's

resulting '986 patent. Jazz and Mr. Valentine did not disclose to the Examiner that Avadel's '321 application was the source of claims in Jazz's '041 application. Jazz and Mr. Valentine's suppression of evidence is an affirmative act of egregious misconduct. Nor did they offer any explanation for why they had not disclosed Avadel's '321 application in their initial IDS.

ANSWER: Jazz Pharmaceuticals admits that the applicants for the '041 application disclosed Avadel's '986 patent and the published '321 application to the PTO in an Information Disclosure Statement filed on April 27, 2021, refers to the text, claims, and file history of the '041 application for the contents thereof, and, except as so admitted, otherwise denies the allegations of paragraph 39.

40. On May 20, 2021, Mr. Valentine filed and signed an Amendment and Request for Reconsideration after Non-Final Rejection to overcome prior art relied on by the Examiner to reject the claims in Jazz's '041 application as obvious. Included with this filing in support of Jazz's attempt to overcome the obviousness rejections was a signed declaration of named inventor Clark Allphin that addressed technical issues and the prior art cited by the Examiner. In his declaration, Mr. Allphin represented that the '041 application was entitled to a 2015 filing date, *i.e.*, the date of the '889 provisional application. *See* Allphin Declaration at ¶ 5 ("In fact, when the present application was filed in 2015 . . ."). Mr. Allphin also declared that the references relied upon by the Examiner did not render the pending claims obvious because, among other reasons, they were not about using oxybate in sachet form for once-a-day administration. *See* Allphin Declaration at ¶¶ 7-8 ("No cited reference describes or suggests administering a solid oxybate formulation in a sachet dosage form let alone according to a once-a-day administration schedule. . . . *Alshaikh* does not suggest using a sachet dosage form *Luhn* does not relate to oxybate at all"). Mr. Allphin also represented that "according to *Luhn*, sachets are common in the confectionary field but less so in pharmaceutical industry because of regulatory and manufacturing challenges." *Id.* at ¶ 8. Mr. Allphin also declared that in his experience, "pharmaceutical developers prefer to rely on known, proven technologies for product development." *Id.* Mr. Valentine repeated these arguments and directed the Examiner to the Allphin declaration in the May 20, 2021 submission that he signed.

ANSWER: Jazz Pharmaceuticals admits that the applicants for the '041 application filed an amendment and response to a non-final office action on May 20, 2021 which contained a declaration from the co-inventor Clark Allphin, that the '041 application is entitled to a priority date of February 18, 2015 based on the filing of the '889 application, refers to the text, claims, and file history of the '041 application for the contents thereof, and, except as so admitted, otherwise denies the allegations of paragraph 40.

41. Neither the Amendment and Request for Reconsideration signed by Mr. Valentine nor the declaration signed by Mr. Allphin disclosed the claim copying or that Avadel's '321 application (which by then had issued as the '986 patent) was the source of the first seven claims of Jazz's '041 application. Instead, Mr. Valentine and Mr. Allphin continued to intentionally withhold this information from the Examiner, and thus engaging in affirmative egregious misconduct. Nor did they disclose that their sworn statement that "no cited reference describes or suggests administering a solid oxybate formulation in a sachet dosage form let alone according to a once-a-day administration schedule" was false, because Avadel's '321 application described exactly that. Jazz's submission of an unmistakably false affidavit is an affirmative act of egregious misconduct.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 41.

42. Mr. Allphin and Mr. Valentine also did not inform the Examiner that, contrary to Mr. Allphin's assertion that pharmaceutical companies would not develop a sachet form of oxybate, Avadel was developing a sachet form of oxybate, and that indeed, the pending claims were copied from an Avadel patent application on that very subject.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 42.

43. Mr. Valentine participated throughout the prosecution of the Jazz's '041 application that issued as the '079 patent, including signing amendments and remarks, IDSs, and participating as attorney of record for Jazz in Examiner interviews.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 43.

44. On information and belief, Mr. Valentine was aware of Avadel's '321 application and its claims before Jazz's '041 application was filed.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 44.

45. Mr. Valentine had a duty to disclose the source of the '041 application claims and the claim copying to the Examiner under Manual of Patent Examining Procedure 2001.06(d) [R-08.2017] and 37 CFR 11.804 and 78 FR 20179 at 20188. That duty was independent of a general duty to disclose prior art. Applicants and their counsel have a separate, independent duty to call the PTO's attention to the fact that they have copied their patent claims from another source. On information and belief, Mr. Valentine intentionally withheld this information from the Examiner and failed to comply with his duty of disclosure.

ANSWER: Paragraph 45 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 45.

46. A patent applicant has a duty to disclose the true and correct inventors of the claimed invention. Jazz deliberately misled the PTO as to the true and correct inventors, and has therefore engaged in affirmative acts of egregious misconduct. The named inventors of the '079 patent did not invent the first seven claims of Jazz's '041 application that resulted in the '079 patent. Rather, on information and belief, Mr. Valentine copied, and in some cases slightly modified, the first seven claims from Avadel's published '321 application and used those claims as the basis for the first 7 claims of Jazz's '041 application. Mr. Valentine did not tell the patent Examiner for the '041 application that he had copied Jazz's '041 application claims from Avadel's published '321 application, and instead withheld this fact from the Examiner. Nor did the named inventors of the '041 application invent a once-nightly sachet formulation that is the basis of those claims. Rather, they copied the invention from the true inventors – Claire Megret, Herve Guillard, and Jean-Fancois Dubuisson, who filed Avadel's '321 application. Instead, the Jazz actors, including at least Mr. Valentine, wrongly resubmitted an inaccurate inventor's oath claiming that the named inventors were the "original inventor or an original joint inventor of a claimed invention in the application" of the subject matter at issue. *See, e.g.*, MPEP 2157 ("Where an application names an incorrect inventorship, the applicant should submit a request to correct inventorship under 37 CFR 1.48").

ANSWER: Paragraph 46 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 46.

47. Even if Jazz had not deliberately copied the invention from Avadel and intentionally withheld that fact from the patent Examiner, its deliberate decision to withhold the '321 application during the initial IDS and the main substantive patent prosecution was independently inequitable conduct. The Avadel '321 application was unquestionably the closest piece of prior art to the claimed invention. Indeed, as shown above, it was virtually identical. It was prior art, having an earlier filing date than Jazz's application and indeed an earlier filing date than Jazz's parent application. And there is no question that Mr. Valentine was aware of the application from the outset of prosecution. Jazz's deliberate decision to withhold the most relevant piece of prior art until after filing a motion for reconsideration mere weeks before the patent issued, while disclosing more than 200 less relevant references, was calculated to hide from the Examiner a prior art reference that unquestionably anticipated the claims.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 47.

**Avadel's Allegation that It is Entitled to A Declaratory Judgment of
Unenforceability of the '079 Patent Due to Jazz's Inequitable Conduct**

48. As is clear from the similarity of the first seven published claims in Avadel's '321 application and the first seven claims in Jazz's later filed '041 application, Mr. Valentine knew of the patent claims from Avadel's '321 application that were made publicly available in October 2020.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 48.

49. Mr. Valentine copied the first seven claims of Avadel's '321 application as the basis for the first seven claims of Jazz's '041 application that issued as the '079 patent.

ANSWER: Jazz Pharmaceuticals refers to the text, claims, and file history of the '041 application for the contents thereof, and otherwise denies the allegations of paragraph 49.

50. Jazz and Mr. Valentine sought to hide this copying from the Examiner, Avadel, and the public for as long as possible.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 50.

51. Mr. Valentine attempted to hide the claim copying from the Examiner by filing the December 21, 2020 IDS with 204 references but intentionally omitting from that IDS Avadel's '321 application that was the source of claims in Jazz's '041 application, even though Mr. Valentine knew of Avadel's '321 application before filing the December 21, 2020 IDS.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 51.

52. Jazz and Mr. Valentine further sought to hide the claim copying from Avadel and the public by filing a Nonpublication Request. Jazz and Mr. Valentine knew that if the claims in Jazz's '041 application were public, Jazz's copying of Avadel's claims would be immediately apparent to Avadel, and Avadel would have been able to file a derivation proceeding challenging Jazz's effort to copy its invention. By hiding the '041 application and the copied claims from public view, Jazz and Mr. Valentine prevented Avadel from filing a derivation proceeding and kept the claim copying and issuance secret.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 52.

53. Mr. Valentine's failure to notify the PTO of the copied claims combined with Jazz's Nonpublication Request was the but-for cause of the issuance of at least claims 1-7 of the '079 patent. On information and belief, the Examiner would not have issued those claims had they been aware that the invention was copied from the earlier-filed Avadel '321 application and that Claire Megret, Herve Guillard, and Jean-Fancois Dubuisson were the true inventors.

ANSWER: Paragraph 53 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 53.

54. Mr. Valentine did not disclose this claim copying to the PTO. Instead, Mr. Valentine intentionally withheld this claim copying and the true source of claims of Jazz's '041 application from the PTO Examiner who examined the '041 application. Upon information and belief, Mr. Valentine withheld this information from the PTO Examiner with the intent to deceive the Examiner into thinking the named inventors of the '079 patent had come up with the original claims from Jazz's '041 application for which they were the purported inventors. That is the single most reasonable inference because there is no other reason that would explain Mr. Valentine's deliberate withholding of the most relevant piece of prior art and of the fact that he had copied that prior art directly into the '041 application. Nor is there any reason Jazz would have filed a Nonpublication Request for a patent application whose text was already published except as part of an effort to conceal the fraud and deceive the Examiner.

ANSWER: Paragraph 54 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 54.

55. That Avadel's '321 application was the source of claims of Jazz's '041 application and that Mr. Valentine copied claims from Avadel's '321 application in writing the claims of Jazz's '041 application is but-for material information to Jazz's '041 application. Mr. Valentine knew this information, which he withheld, was but-for material to prosecution of the '079 patent.

ANSWER: Paragraph 55 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 55.

56. Mr. Valentine had a duty to disclose the source of the '041 application claims and the claim copying to the Examiner under Manual of Patent Examining Procedure 2001.06(d) [R-08.2017] and 37 CFR 11.804 and 78 FR 20179 at 20188. Mr. Valentine intentionally withheld this information from the Examiner and failed to comply with his duty of disclosure.

ANSWER: Paragraph 56 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 56.

57. But for Mr. Valentine withholding the source of the '041 application claims and the claim copying from the Examiner, the Examiner would have not approved claims 1-7 of the '079 patent for issuance because those claims were not invented by the named inventors of the '079 patent.

ANSWER: Paragraph 57 states legal conclusions for which no answer is required. To the extent that an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 57.

58. The '079 patent is unenforceable and void because the Jazz actors (including Mr. Valentine) violated the duty of candor and good faith in dealing with the PTO by intentionally and deceptively failing to disclose material information to the PTO during prosecution.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 58.

59. Mr. Valentine engaged in inequitable conduct during prosecution of the '079 patent by knowingly and intentionally withholding material information about the source of Jazz's patent claims from the PTO. But for Mr. Valentine's knowing and intentional failure to submit this material information to the PTO, at least claims 1-7 of the '079 patent would not have issued.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 59.

Count IV: Alleged Unclean Hands

60. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

ANSWER: Jazz Pharmaceuticals incorporates its responses to the preceding paragraphs.

Avadel's Allegation that It is Entitled to A Declaratory Judgment of Unenforceability of the '079 Patent Due to Jazz's Unclean Hands

61. As described above, the named Jazz inventors did not actually invent the subject matter of the claims identified herein, instead copying them from work by the true inventors affiliated with Avadel, falsely swore that they were the true and original inventors, and concealed their misconduct from the patent Examiner in order to obtain the '079 patent. Doing so was misconduct by Jazz that has an immediate and necessary relation to the equity Jazz seeks with respect to this litigation. Thus, Jazz is foreclosed from asserting the '079 patent as a result of its unclean hands.

ANSWER: Jazz Pharmaceuticals denies the allegations of paragraph 59.

62. Avadel seeks a dismissal of the infringement action as to the '079 patent because the unconscionable act of one coming for relief has immediate and necessary relation to the

equity that Plaintiffs seek. Jazz's deception before the PTO relates to that relief for all the reasons stated above, namely, that Jazz misled the PTO into issuing the '079 patent by specifically hiding the fact that the Jazz named inventors did not actually invent the subject matter claimed in the subject claims of the '079 patent. Indeed, Jazz deceived the PTO as to the true inventor of at least claims 1-7 of the '079 patent, concealed its copying of claims in Avadel's '321 application, and buried the reference to Avadel's application. But for Jazz's deceptive conduct, at least claims 1-7 of the '079 patent would not have issued.

ANSWER: Jazz Pharmaceuticals admits that Avadel purports to seek dismissal of the infringement action as to the '079 patent, denies that Avadel is entitled to the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 62.

AVADEL'S PRAYER FOR RELIEF

Jazz Pharmaceuticals denies that Avadel is entitled to any relief on its Counterclaims, either as prayed for in its pleading or otherwise.

JAZZ PHARMACEUTICALS' AFFIRMATIVE DEFENSE

Without prejudice to the denials set forth in this Answer and to the ability to amend this Answer to seek and allege any and all defenses not presently known or that are revealed during the course of discovery or otherwise, Jazz Pharmaceuticals asserts the following affirmative defense in response to Avadel's Counterclaims:

Failure to State a Claim

The Counterclaims fail to state any claim for which relief may be granted.

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CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 30, 2021, upon the following in the manner indicated:

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